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Feld et al.

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(54) **CONSTRAINING STRUCTURE WITH NON-LINEAR AXIAL STRUTS**

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(Continued)

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CPC ***A61B 17/50*** (2013.01); ***A61B 17/320725*** (2013.01); ***A61M 25/104*** (2013.01); *A61M 2025/1084* (2013.01)

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USPC 623/1.11, 1.12, 1.23, 2.11; 606/108, 606/191–200, 159; 604/96.01, 103, 103.03, 604/103.05, 103.06, 103.07, 103.08, 103.09
See application file for complete search history.

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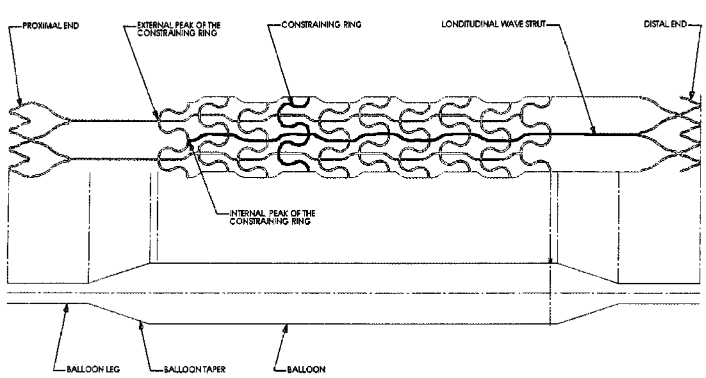
(57) **ABSTRACT**

A constraining structure for use with a balloon catheter can include multiple longitudinal struts and multiple, sinusoidal shaped radial rings. The constraining structure can expand to form a pattern of channels including substantially square windows. The constraining structure can modify, restrict, and control a shape and/or size of the balloon when inflated. Inflating the balloon catheter within the constraining structure can provide nonuniform pressure on a vessel wall adjacent the balloon.

12 Claims, 2 Drawing Sheets



(51) **Int. Cl.**
A61M 25/10 (2013.01)
A61F 2/06 (2013.01)

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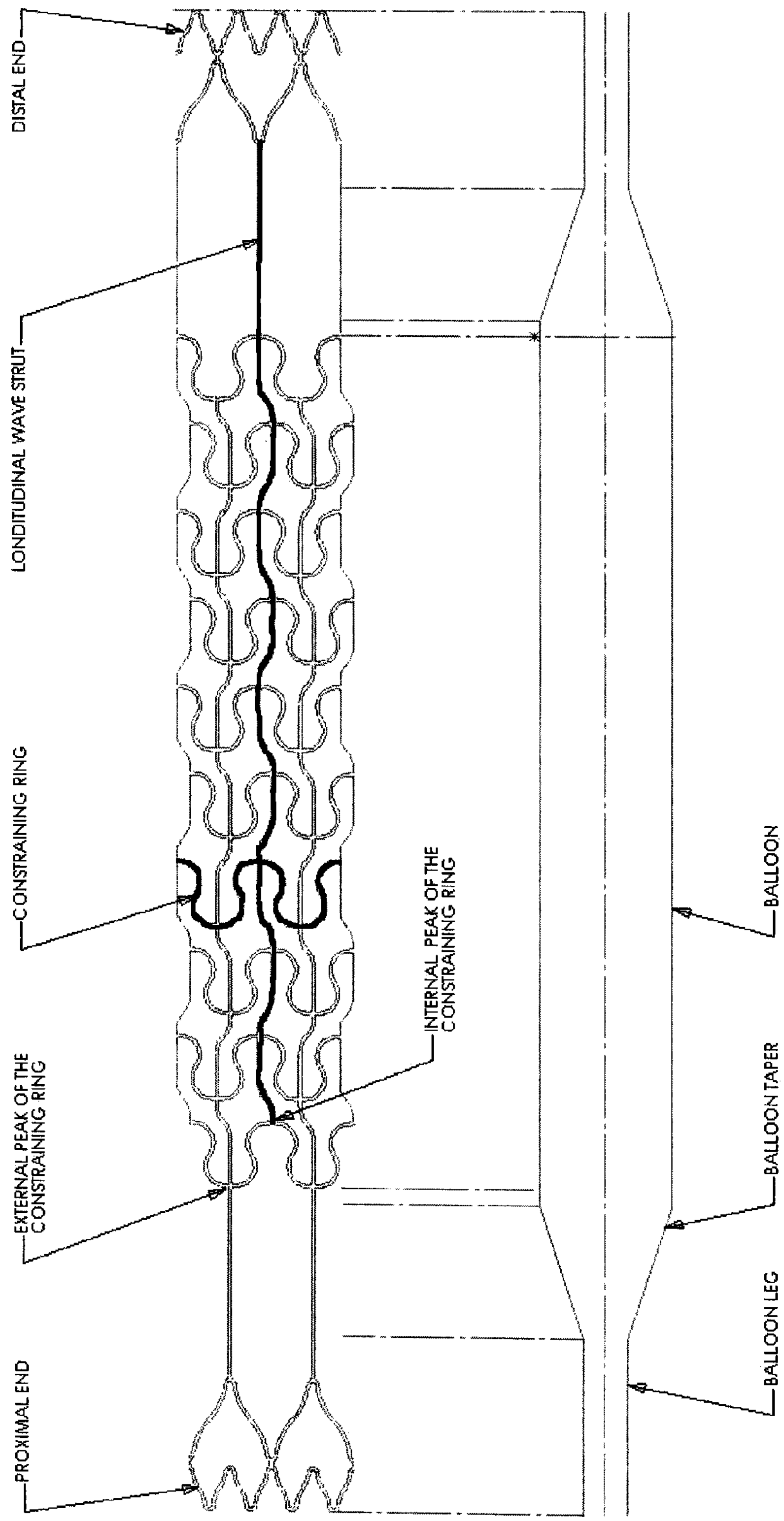
DISTAL END
LONDITUDINAL WAVE STRUT
CONSTRAINING RING
INTERNAL PEAK OF THE CONSTRAINING RING
EXTERNAL PEAK OF THE CONSTRAINING RING
PROXIMAL END
BALLOON
BALLOON TAPER
BALLOON LEG

FIG-1

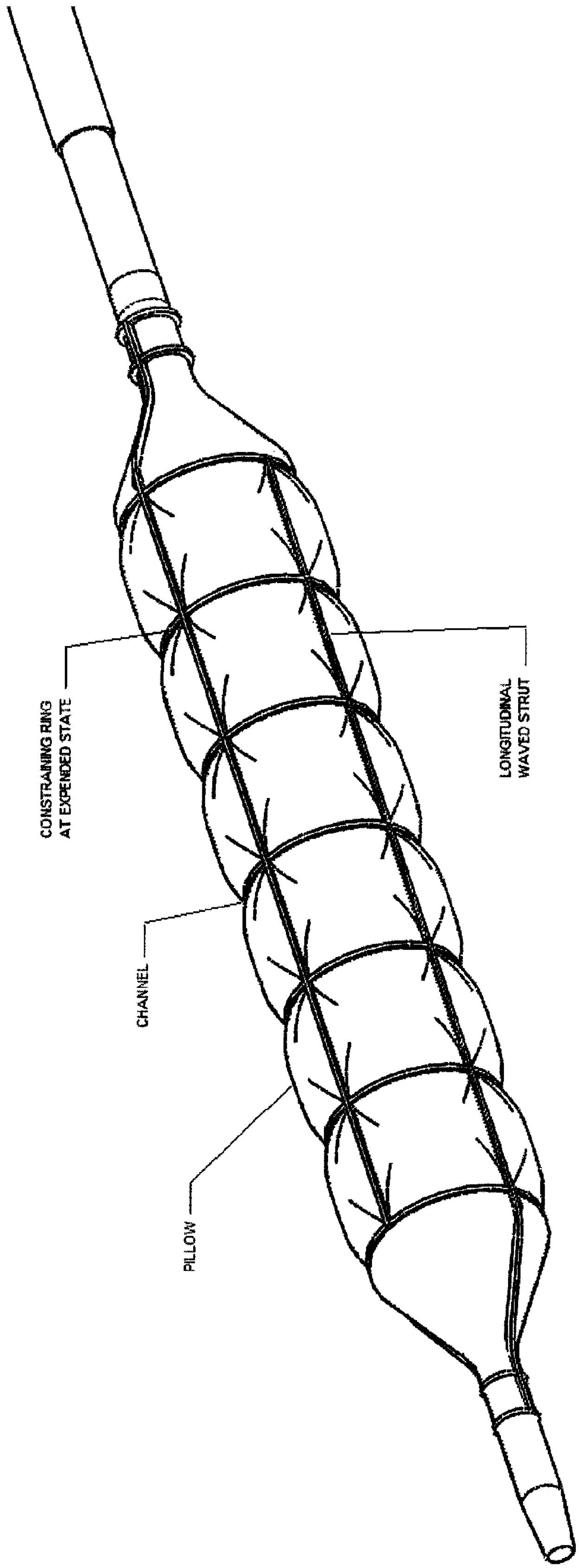
CONSTRAINING RING
AT EXPENDED STATE
LONGITUDINAL
WAVED STRUT
CHANNEL
PILLOW

FIG-2

CONSTRAINING STRUCTURE WITH NON-LINEAR AXIAL STRUTS

This application claims the benefit of U.S. Provisional Application No. 61/596,618, filed Feb. 8, 2012, the entirety of which is incorporated by reference herein.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention is a balloon catheter for angioplasty procedures, comprising an elastic constraining structure mounted over the balloon where the structure has a mechanism of expansion to control the balloon inflation.

Conventional angioplasty balloons expand in an artery lesion at the least resistant areas of the lesion causing "dog bone" effect at the lesion ends and overexpansion in the softer areas, resulting in trauma to the vessel wall. Conventional angioplasty is associated with vessel displacement and its main mechanism of action is plaque compression where the vessel is significantly displaced or "pushed out" before reaction force can be generated and plaque compression takes place. During this process the balloon may expand in the axial direction (in addition to radial), a phenomenon that accelerates propagation of "cracks" in the vessel wall (dissections). This elongation continues after the balloon engages the lesion and the vessel wall and cause longitudinal stretch

This mechanism of action causes a high rate of failure due to the vessel trauma (randomize studies in legs arteries document up to 40% acute failure rate and poor long term results with 20%-40% patency in one year). Attempts to modify the mechanism of action were mainly aimed at increasing the local force by adding cutting blades, wires or scoring elements that can penetrate into the vessel wall and create pre defined dissection plans. Those devices are used when encountering resistant lesions otherwise hard to crack open with conventional balloons. None of those technologies was designed to provide an alternative mechanism that leads to a gentler dilatation by minimizing vessel displacement and reducing the radial forces during balloon dilatation.

SUMMARY OF THE INVENTION

According to the present invention, a device that modifies the properties of an angioplasty balloon in order to provide uniform inflation and extraction of longitudinal forces in order to facilitate plaque extrusion and minimize vessel trauma. In the device presented herein, a novel constraining structure prevents non-cylindrical expansion using constraining rings that are spaced apart along the balloon working length leading to creation of small balloon segments (pillows) separates by grooves that facilitate plaque extrusion. The constraining structure also prevents longitudinal elongation of the balloon since it has a structure that shortens during expansion and constrains the balloon in both longitudinal and radial directions.

Computer simulation shows a decrease in radial forces using a balloon with the constraining structure. The constraining structure causes reduction in the rate of vessel dissections and perforations thru formation of an array of balloon pillows that provide gentle contact with the vessel wall and thru the formation of channels between these pillows that allow plaque flow and strain relief areas in the vessel wall.

Conventional balloon angioplasty does not provide strain relief to the vessel wall and suffer from high rate of dissections.

Other devices, such as cutting balloons and scoring devices (for example U.S. Pat. No. 7,691,119 Farnan) made to address resistant lesions by adding elements that can cut or score into the vessel wall and significantly, increase the local force ("focus force angioplasty"), but do not provide strain relief and gentle contact with the vessel wall. On the contrary, these devices include aggressive metallic components that are made to break hard plaque and mark their metal footprint on the vessel wall.

The constraining structure of the present invention takes advantage of the fact that by forcing the balloon into pillows topography the excessive length of the balloon is directed into a three dimensional shape and the surface area of the balloon increases. This mechanism shortens the overall balloon length during inflation and minimized longitudinal vessel stretch. Other devices such as stents or scoring cages that have structures over a balloon are using the balloon as an "activator" or expandable shell designed to increase the diameter of the stent or scoring stent and allow the balloon to inflate in full both radially and longitudinally and are therefore designed to expand as big as the inflated balloon, while the design present herein is made smaller than the inflated balloon, specifically aimed to modify, restrict and control the balloon inflated shape and size.

The combination of the advantages of the device described herein result in controlled non aggressive and predictable lesion dilation that addresses a major health concern.

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** show the layout of the constraining structure design adjacent to the balloon scheme, where the distal and proximal ends of the constraining structure are placed over the balloon legs, the constraining rings are spaced apart along the balloon length over the working length of the balloon, and an array of longitudinal waved struts interconnect between the constraining rings and the ends.

FIG. **2** shows a scheme of the inflated device with circumferential and longitudinal pattern of channels and pillows.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

A balloon catheter comprising a catheter shaft and an inflatable balloon at its distal end and an elastic constraining structure is mounted over the balloon. The constraining structure is made from an elastic material such as Nitinol, elastic polymers or high strength fibers or mesh.

The device natural configuration is collapsed. Unlike "self-expanding stents," it is not"self-expanding" but to the contrary "self-closing" prior to expansion the constraining structure is tightly closed on the folded balloon. When the balloon is inflated the constraining structure is expanded by the balloon force up to a diameter smaller than the free inflated diameter of the balloon. The structure will self compress back to a small diameter when the balloon is deflated. Typically the distal end and a proximal end of the constraining structure are fixedly attached to the catheter at both sides of the balloon to prevent it from disengaging with the catheter. Attachment is made by means of adhesive or thermal bonding or other method known in the art.

The constraining structure comprises an array of sinusoidal constraining rings spaced apart along the balloon working length. Each ring has a sinus curve length defined by the length of the ring when fully straitened. For each ring the sinus curve length is smaller than the balloon expanded circumference. When expanded the rings expand to its maximal expansion resulting in a substantially circular ring shape that is smaller in diameter than the balloon diameter and force a substantially circular channel around the balloon outer surface.

Expansion of the constraining rings results in an array of channels along the balloon length and also results in shortening of the balloon. It is easier to understand the shortening caused by the rings as it is obvious that if the rings were removed from an inflated balloon the balloon would elongate.

The maximum expanded diameter of the constraining structure is mainly controlled by the length of the sinus curve rings. The maximum expanded diameter could be 0.15 mm-0.3 mm smaller than the balloon free inflated diameter but it could also be in the range of 0.1 mm to 0.5 mm or exceed this range depending on the material of choice and the specifics of the design. For example for 3 mm balloon the maximum expanded diameter of the structure made of nitinol is in the range of 2.6 mm-2.85 mm. If the maximum expanded diameter is out of the desirable range the device will fail to perform. For example, if the maximum expanded diameter is similar or larger than the balloon free expanded diameter, the constraining structure would not be able to restrict the free expansion of the balloon and pillows will not form. If the structure is too small, the forces applied by the balloon would cause the structure to break and the device will fail, risking patient's safety.

The constraining rings are interconnected by a circumferential array of interlacing longitudinal waved struts. The number of struts is usually twice the number of the sine waves in the constraining ring. For example the structure scheme shows a two waves sine ring and therefore four longitudinal waved struts. Each strut begins near one end of the constraining structure and ends at the last constraining ring near the opposite end. It does not continue all the way to the opposite end in order to allow proper functionality and expansion. The following strut begins near the opposite end of the constraining structure and ends at the last constraining rings near the first end of the balloon, such that the opposing ends are not interconnected by the longitudinal waved struts.

This construction result in the last ring being connected to the ends with half the number of struts only. If the struts were to continue all the way to the opposing end it would restrict the first ring from expanding homogeneously over the balloon as the intermediate rings expand.

The struts connect to the first constraining rings at the external peaks of the ring and thus forming a structure that shortens when expanded. If the struts were connected to the first constraining rings at the internal peaks of the ring than the structure would elongate when expanded.

It is particularly important not to have "spine" or struts that are connected to both proximal and distal end of the balloon. The current structure in FIG. **1** in which two (or more) longitudinal struts are connected to the distal end of the balloon and two (or more) other interlacing struts connected to the proximal end of the balloon create "push/pull" forces during

inflation and longitudinal struts are moving in opposing directions during inflation in order to apply compressive forces on the balloon and allow it to shorten. This "tilt" function supports expansion of the pillows at lower pressure. The longitudinal waved struts form longitudinal channels over the balloon outer surface and together with the circular channels formed by the rings it results in substantially square pattern of channels ("windows") and balloon pillows protruding in the windows.

What is claimed is:

1. A balloon catheter, comprising

a catheter body;

a constraining structure comprising:

a plurality of expandable, radial rings spaced apart along a length of the constraining structure, said plurality of radial rings comprising a proximal end ring and a distal end ring;

a plurality of longitudinal struts spaced along a circumference of the constraining structure, the plurality of longitudinal struts comprising a first longitudinal strut and a second longitudinal strut, a first end of the first longitudinal strut attached to the catheter body and a second end of the first longitudinal strut attached to said proximal end ring, a first end of the second longitudinal strut attached to the catheter body and a second end of the second longitudinal strut attached to said distal end ring,

wherein the constraining structure is configured to be positioned over the balloon catheter and wherein the constraining structure has an expanded and a collapsed state and is biased to be in the collapsed state, and

wherein the first longitudinal strut moves in a first axial direction and the second longitudinal strut moves in a second axial direction during expansion of the constraining structure, the second axial direction being opposite the first axial direction.

2. The balloon catheter of claim **1**, wherein the radial rings comprise one or more first peaks extending towards a proximal end of the constraining structure and one or more second peaks extending towards a distal end of the constraining structure.

3. The balloon catheter of claim **1**, wherein each longitudinal strut is attached to a peak of the radial ring closest to its point of attachment to the catheter body.

4. The balloon catheter of claim **1**, wherein the radial rings comprise one or more sine waves.

5. The balloon catheter of claim **4**, wherein the number of struts is twice a number of longitudinal sine waves in the radial rings.

6. The balloon catheter of claim **1**, wherein the longitudinal struts are waved struts.

7. The balloon catheter of claim **1**, wherein the first longitudinal strut is attached to the catheter body by a distal end of the constraining structure, and wherein the second longitudinal strut is attached to the catheter body by a proximal end of the constraining structure.

8. A method of expanding a balloon catheter in a vessel of a patient, the method comprising:

positioning the balloon catheter so that a balloon of the balloon catheter is adjacent a treatment site in a vessel of a patient, the balloon catheter comprising a catheter body and a constraining structure positioned over the balloon, the constraining structure comprising a plurality of longitudinal struts connecting a plurality of radial sinusoidal rings, the plurality of rings comprising a proximal end ring and a distal end ring, the plurality of longitudinal struts comprising a first longitudinal strut and a second longitudinal strut, a first end of the first longitudinal strut attached to the catheter body and a second end of the first longitudinal strut attached to the proximal end ring, a first end of the second longitudinal strut attached to the catheter body and a second end of the second longitudinal strut attached to said distal end ring, the constraining structure biased to be in a collapsed state; and

inflating the balloon, thereby expanding the constraining structure and providing nonuniform pressure on a wall of the vessel adjacent the balloon, the first longitudinal strut moving in a first axial direction and the second longitudinal strut moving in a second axial direction during expansion of the constraining structure, the second axial direction being opposite the first axial direction.

9. The method of claim **8**, wherein inflating the balloon and expanding the constraining structure produces a pattern of channels comprising a pattern of substantially square windows in the constraining structure.

10. The method of claim **9**, wherein inflating the balloon and expanding the constraining structure causes balloon pillows to protrude through said substantially square windows.

11. The method of claim **8**, wherein expanding the constraining structure comprises expanding the constraining structure in a radial direction.

12. The method of claim **8**, wherein expanding the constraining structure comprises at least one of modifying, restricting, and controlling a shape and/or size of the balloon when inflated.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 9,179,936 B2
APPLICATION NO. : 13/761525
DATED : November 10, 2015
INVENTOR(S) : Tanhum Feld

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

In column 2 at line 62, Change “not”self-expanding”” to --not “self-expanding”--.

In the Claims

In column 4 at line 48, In Claim 5, after “number of” insert --longitudinal--.

In column 4 at line 49, In Claim 5, change “a” to --the--.

In column 4 at line 49, In Claim 5, after “number of” delete “longitudinal”.

Signed and Sealed this
Seventh Day of June, 2016

Michelle K. Lee

Michelle K. Lee
Director of the United States Patent and Trademark Office